Zacks Small-Cap Research

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# Grace Therapeutics, Inc. (GRCE: NASDAQ)

## *GRCE: Progress Report*

Grace's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. Additionally, we apply an 85% probability of commercial success to the GTx-104 program. The adjustment recognizes regulatory and commercialization risks. The model includes contributions from the United States and the developed world.

| | |
|---|---|
| Current Price (6/4/2025) | $2.88 |
| **Valuation** | **$12.50** |

## OUTLOOK

Grace is a clinical-stage, biotechnology company focused on rare disease. Its lead program, GTx-104, is a novel injectable formulation of nimodipine for the treatment of aneurysmal subarachnoid hemorrhage (aSAH). Other programs include GTX-102 for Ataxia Telangiectasia & GTX-101 for postherpetic neuralgia. GTX-104 is formulated from a previously approved product and a patented technology that employs non-ionic surfactant micelles to overcome delivery shortcomings.

Nimodipine is a lipophilic calcium channel blocker that has been shown to be effective in improving outcomes following aSAH surgery. Its FDA approved oral formulation presents several drawbacks especially for patients who have difficulty swallowing. An IV formulation using safe excipients can address many of these challenges and is represented by GTX-104.

GTX-104 has reported data from its pivotal Phase III safety trial and is expected to submit an NDA mid-2025. Other candidates are ready for Phase III (GTX-102) & Phase II (GTX-101) and are available for partnering or further development if additional capital becomes available.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **4.97** |
| **52-Week Low** | **1.75** |
| **One-Year Return (%)** | **-0.7** |
| **Beta** | **0.9** |
| **Average Daily Volume (sh)** | **26,160** |
| **Shares Outstanding (mil)** | **15.9** |
| **Market Capitalization ($mil)** | **45.8** |
| **Short Interest Ratio (days)** | **0.6** |
| **Institutional Ownership (%)** | **39.7** |
| **Insider Ownership (%)** | **38.4** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2025 Estimate** | **N/A** |
| **P/E using 2026 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Average** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Biomed/Gene** |

## ZACKS ESTIMATES

### Revenue

(In millions of US$)

| | Q1 (Jun) | Q2 (Sep) | Q3 (Dec) | Q4 (Mar) | Year (Mar) |
|---|---|---|---|---|---|
| 2024 | $0.0 A | $0.0 A | $0.0 A | $0.0 A | $0.0 A |
| 2025 | $0.0 A | $0.0 A | $0.0 A | $0.0 E | $0.0 E |
| 2026 | | | | | $0.0 E |
| 2027 | | | | | $1.4 E |

### Earnings per Share

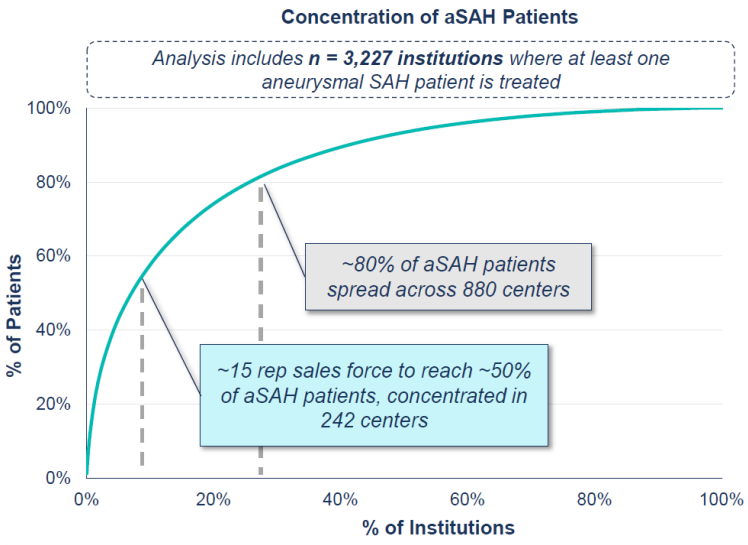
| | Q1 (Jun) | Q2 (Sep) | Q3 (Dec) | Q4 (Mar) | Year (Mar) |
|---|---|---|---|---|---|
| 2024 | -$0.54 A | -$0.43 A | -$0.21 A | -$0.34 A | -$1.35 A |
| 2025 | -$0.24 A | -$0.30 A | -$0.36 A | -$0.20 E | -$0.98 E |
| 2026 | | | | | -$0.63 E |
| 2027 | | | | | -$0.44 E |

## What's New?

Grace Therapeutics, Inc (NASDAQ: GRCE) will soon submit its new drug application (NDA) to the FDA, which we expect in the next few weeks. The company recently held a pre-NDA meeting with the FDA and came away feeling closely aligned with the agency in terms of what is required for NDA acceptance. The company is in a strong position as it makes its application with a balance sheet with approximately $20 million as of March 31st, 2025 and a product that meets a profound unmet need. During previous equity capital raises, Grace was able to structure these deals so that the attached warrants could be called upon achieving certain milestones. The company will be able to demand exercise of warrants that can potentially generate about $7.6 million following NDA acceptance and about $15 million following approval of GTx-104 assuming the warrants are in the money.

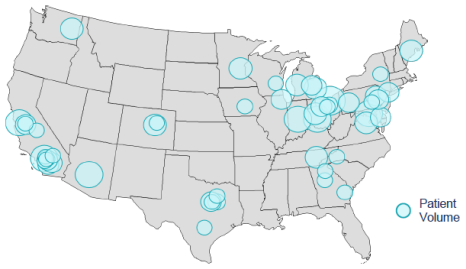
With the funds on the balance sheet and additional capital raised from the warrant exercises, Grace will be able to begin commercialization activities. Its plan is to focus on the top 250 to 300 hospitals that address aneurysmal subarachnoid hemorrhage (aSAH), which is achievable with a sales force of 15 to 20. We expect to hear more about the strategy following NDA submission and the conclusion of marketing studies the company is conducting.

**Exhibit I – Concentration of aSAH Care**




**aSAH-Treating Institutions Concentration**

| % aSAH Patients | % of Institutions | # of Institutions | Est. Sales Reps[1] |
|---|---|---|---|
| 40% | ~4% | 146 | ~10 |
| 50% | ~7% | 242 | ~15 |
| 60% | ~11% | 380 | ~25 |




Source: Grace Therapeutics Overview, April 2025

*Investment Thesis*

Grace's GTx-104 investment thesis is straightforward. There are about 40,000 aSAH cases per year in the United States that in many cases are inadequately served. Oral nimodipine is standard of care. The underlying drug has demonstrated its efficacy in increasing blood flow to the brain, reducing brain damage and improving neurological outcomes. However, nimodipine is only available in oral form which presents several shortcomings. The primary weakness is that the oral formulation is difficult to administer to patients that are unconscious or have a hard time swallowing, which is a common feature of aSAH patients. Oral nimodipine should be administered every four hours due to its short half-life and it should not be taken with food as this reduces its already low bioavailability. Nimodipine's oral bioavailability is low and variable, with extensive first-pass hepatic metabolism and poor solubility contributing to reduced systemic exposure. Higher blood plasma levels can cause hypotension which is associated with neurological impairment, organ damage, reduced kidney function and other risks. Europe offers an IV formulation of nimodipine branded Nimotop; however, the product solubilizes the drug with high levels of ethanol and propylene glycol. These excipients have numerous negative effects and prevented FDA approval of Nimotop. Grace's IV formulation uses excipients generally recognized as safe (GRAS), and provides a product which is able to improve upon the ethanol-based European version and the oral formulation's primary weaknesses.

Results from Grace's Phase III safety trial found excellent relative dose intensity, better outcomes, fewer intensive care unit readmissions and fewer ventilator days for GTx-104 compared with oral nimodipine. The trial met its primary endpoint of the number of patients with at least one episode of clinically significant hypotension reasonably considered to be caused by the drug. Patients receiving GTx-104 experienced a 19% reduction in at least one incidence of clinically significant hypotension compared to oral nimodipine (28% versus 35%). Secondary endpoints include safety, clinical and pharmacoeconomic outcomes. Additional detail on the trial can be found in Grace's press release and in our report.

We assign Grace a $12.50 valuation which provides upside of over 4x. It is a relatively lower risk development play as the underlying drug is already approved, the new formulation addresses significant unmet needs and all of the development work is complete, generating compelling results. While the company plans to develop GTx-104 itself, we think that additional value could be recognized if an established pharmaceutical company buys the asset and folds it into its operations.

**The Company**

Grace is a clinical-stage, biotechnology company focused on rare disease. Its lead program is advancing GTx-104, a novel injectable formulation of nimodipine for the treatment of aneurysmal subarachnoid hemorrhage (aSAH). GTx-104 is an intravenous (IV) formulation of nimodipine that is a better alternative to the oral version for treating patients that are unconscious or unable to swallow, which is common for those suffering from an aSAH. Nimodipine is approved for subarachnoid hemorrhage due to its ability to prevent vasoconstriction following an aneurysm. In several studies, the drug has demonstrated that it can improve neurological outcomes and boost recovery in aSAH patients. Despite its benefits, approved nimodipine presents several shortcomings due to its oral formulation which makes it difficult to deliver to unconscious patients. Low bioavailability and other drug characteristics contribute to highly variable levels of blood plasma levels. The variability can lead to hypotension and poor outcomes.

aSAH affects up to 40,000 individuals in the United States every year and has a global incidence ranging from 9 to 11 per 100,000 persons. Women are more likely than men to suffer the rupture and the highest incidence occurs around a person's sixth decade. Symptoms of the condition include a sudden, severe headache, neck stiffness, nausea and vomiting among others. The patient should immediately go to the emergency room where he or she will be triaged to diagnose aSAH and to transport them to a specialized center such as a neurointensive care unit (Neuro-ICU). After diagnosis treatment includes surgical clipping or endovascular coiling. After the patient is stabilized with an emphasis on strict blood pressure control, he or she is administered oral nimodipine to prevent vasospasm over the next two or three weeks. This allows sufficient blood flow in the brain to protect brain tissue and allow for effective healing.

Grace recently completed its Phase III STRIVE-ON trial and is planning to submit its NDA via the 505(b)(2) pathway. Based on the company's commentary we see submission in the next month, acceptance of the NDA by late summer and a target action date by mid-2025.

**Milestones**

- Pre-NDA meeting with FDA – 2Q:25
- NDA submission to FDA – mid-2025
- $7.6 million warrant exercise if NDA accepted & above $3.00 strike – Fall 2025
- Target Action Date – mid-2026
- $15 million warrant exercise if GTx-104 approved & above $3.39 – Fall 2026
- GTx-104 commercialization – late 2026

**Resources**

- Initiating Coverage – From Confusion to Infusion – November 2024
- aSAH key opinion leader summary – December 2024
- STRIVE-ON results – February 2025

**Summary**

Grace is valued at less than $40 million, with half of this value in cash on its balance sheet. The company holds no debt and is on the cusp of submitting its NDA to the FDA in the next few weeks. We think product sales could peak at several hundred million dollars, which suggests substantial upside even with a low single-digit multiple of sales. GTx-104 addresses many of the shortcomings of oral nimodipine in treating aSAH and we think it is an easy sell to hospitals as it can significantly improve outcomes and help hospitals maintain their reputations and stroke center certifications. With results from its Phase III safety trial ready and the pre-NDA meeting under its belt, Grace will soon submit its NDA to the FDA and should see a target action date in mid-2026. We maintain our valuation of $12.50 per share.

## PROJECTED FINANCIALS

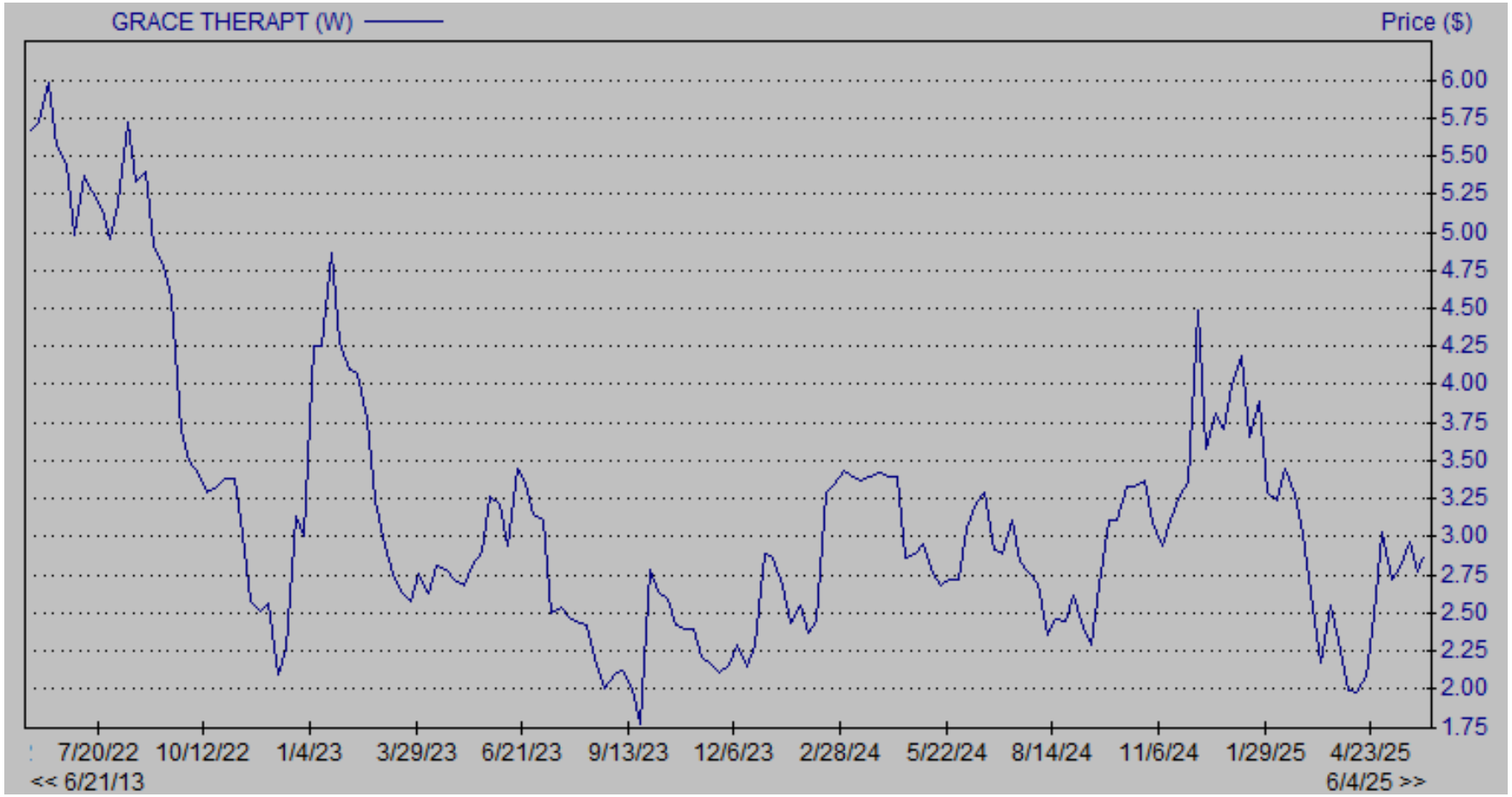
**Grace Therapeutics, Inc. - Income Statement**

| Grace Therapeutics, Inc. | 2024 A | Q1 A | Q2 A | Q3 A | Q4 E | 2025 E | 2026 E | 2027 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues ($USD)** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$1,363** |
| Research & Development | $4,683 | $2,708 | $2,976 | $2,194 | $1,200 | $9,078 | $2,800 | $1,000 |
| General & Administrative | $6,432 | $2,255 | $1,855 | $1,510 | $1,500 | $7,120 | $7,200 | $8,000 |
| Sales & Marketing | $252 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Income from Operations | ($11,367) | ($4,963) | ($4,831) | ($3,704) | ($2,700) | ($16,198) | ($10,000) | ($7,637) |
| Restructuring & Impairments | $1,485 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Other Items | ($2,744) | $1,387 | $375 | ($1,194) | $0 | $568 | $0 | $0 |
| Net Interest Expense | $911 | $235 | $172 | $138 | $0 | $545 | $0 | $0 |
| Pre-Tax Income | ($14,685) | ($3,341) | ($4,284) | ($4,760) | ($2,700) | ($15,085) | ($10,000) | ($7,637) |
| Provision for Income Tax | $1,832 | $724 | $852 | $605 | $378 | $2,559 | $1,400 | $1,069 |
| *Tax Rate* | *-12.5%* | *-21.7%* | *-14.0%* | *-14.0%* | *-14.0%* | *-17.0%* | *-14.0%* | *-14.0%* |
| **Net Income** | **($12,853)** | **($2,617)** | **($3,432)** | **($4,155)** | **($2,322)** | **($12,526)** | **($8,600)** | **($6,568)** |
| *Net Margin* | | | | | | | | |
| **Reported EPS** | **($1.35)** | **($0.24)** | **($0.30)** | **($0.36)** | **($0.20)** | **($1.10)** | **($0.63)** | **($0.44)** |
| *YOY Growth* | | | | | | | | |
| Basic Shares Outstanding | 9,529 | 10,929 | 11,506 | 11,506 | 11,600 | 11,385 | 13,560 | 15,000 |

*Source: Company Filing // Zacks Investment Research, Inc. Estimates*

## HISTORICAL STOCK PRICE

**Grace Therapeutics, Inc. – Share Price Chart[1]**




[1] Source: Zacks Research System

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